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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/616,082	07/08/2003	Stephen Hamilton	GFI/107	9644

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FISH & NEAVE IP GROUP
ROPES & GRAY LLP
1251 AVENUE OF THE AMERICAS FL C3
NEW YORK, NY 10020-1105

EXAMINER	
JOIKE, MICHELE K	

ART UNIT	PAPER NUMBER
1636	

DATE MAILED: 02/10/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/616,082	HAMILTON, STEPHEN	
	Examiner	Art Unit	
	Michele K. Joike, Ph.D.	1636	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *08 July 2003*.

2a)☐ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-56* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *1-56* are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Election/Restrictions

Restriction to one of the following inventions is required under 35 U.S.C. 121:

I. Claims 1, 5-30, drawn to a method for producing a human-like glycoprotein, classified in class 435, subclass 74.

II. Claims 2-30, drawn to a method for producing a N-glycan, classified in class 435, subclass 85.

III. Claims 31-38, 56, drawn to a nucleic acid library wherein the mannosidase catalytic domain is *Arabidopsis thaliana* Mannosidase II, classified in class 435, subclass 6.

IV. Claims 31-38, 56, drawn to drawn to a nucleic acid library wherein the mannosidase catalytic domain is *C. elegans* Mannosidase II, classified in class 435, subclass 6.

V. Claims 31-38, 56, drawn to drawn to a nucleic acid library wherein the mannosidase catalytic domain is *Ciona intestinalis* Mannosidase II, classified in class 435, subclass 6.

VI. Claims 31-38, 56, drawn to drawn to a nucleic acid library wherein the mannosidase catalytic domain is *Drosophila* Mannosidase II, classified in class 435, subclass 6.

VII. Claims 31-38, 56, drawn to drawn to a nucleic acid library wherein the mannosidase catalytic domain is Human Mannosidase II, classified in class 435, subclass 6.

VIII. Claims 31-38, 56, drawn to drawn to a nucleic acid library wherein the mannosidase catalytic domain is Mouse Mannosidase II, classified in class 435, subclass 6.

IX. Claims 31-38, 56, drawn to drawn to a nucleic acid library wherein the mannosidase catalytic domain is Rat Mannosidase II, classified in class 435, subclass 6.

X. Claims 31-38, 56, drawn to drawn to a nucleic acid library wherein the mannosidase catalytic domain is Human Mannosidase IIx, classified in class 435, subclass 6.

XI. Claims 31-38, 56, drawn to drawn to a nucleic acid library wherein the mannosidase catalytic domain is insect cell Mannosidase III, classified in class 435, subclass 6.

XII. Claims 31-38, 56, drawn to drawn to a nucleic acid library wherein the mannosidase catalytic domain is Human lysosomal Mannosidase II, classified in class 435, subclass 6.

XIII. Claims 31-38, 56, drawn to drawn to a nucleic acid library wherein the mannosidase catalytic domain is Human cytoplasmic Mannosidase II, classified in class 435, subclass 6.

XIV. Claims 39-40, 42, 44-46, drawn to chimeric polypeptide and host cell, classified in class 435, subclass 210.

XV. Claims 41, 43-46, drawn to a nucleic acid encoding a chimeric polypeptide and host cell, classified in class 435, subclass 210.

XVI. Claim 47, drawn to a glycoprotein, classified in class 530, subclass 350.

XVII. Claims 48-49, drawn to an N-glycan, classified in class 530, subclass 350.

XVIII. Claim 50, drawn to a nucleic acid sequence of *C. elegans*, classified in class 536, subclass 23.1.

XIX. Claim 51, drawn to a nucleic acid sequence of rat, classified in class 536, subclass 23.1.

XX. Claim 52, drawn to a nucleic acid sequence of *Ciona*, classified in class 536, subclass 23.1.

XXI. Claim 53, drawn to a nucleic acid sequence of *Arabidopsis*, classified in class 536, subclass 23.1.

XXII-XLII. Claims 54-55, drawn to nucleic acid sequences SEQ ID NOs: 5-15 and 49-59, classified in class 536, subclass 23.1.

Claim 31 link(s) inventions III, IV, V, VI, VII, VIII, IX, X, XI, XII and XIII. The restriction requirement among the linked inventions is subject to the nonallowance of the linking claim(s), claim 31. Upon the allowance of the linking claim(s), the restriction requirement as to the linked inventions shall be withdrawn and any claim(s) depending from or otherwise including all the limitations of the allowable linking claim(s) will be

entitled to examination in the instant application. Applicant(s) are advised that if any such claim(s) depending from or including all the limitations of the allowable linking claim(s) is/are presented in a continuation or divisional application, the claims of the continuation or divisional application may be subject to provisional statutory and/or nonstatutory double patenting rejections over the claims of the instant application. Where a restriction requirement is withdrawn, the provisions of 35 U.S.C. 121 are no longer applicable. *In re Ziegler*, 44 F.2d 1211, 1215, 170 USPQ 129, 131-32 (CCPA 1971). See also MPEP § 804.01.

The inventions are distinct, each from the other because of the following reasons:

Inventions I and II are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions comprise method steps with different starting compounds, which will result in end products that are structurally and biochemically unrelated. A search of one would not be co-extensive with a search of the other and hence would be burdensome.

Inventions III-XII and XIII are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions comprise nucleic acid libraries with a mannosidase catalytic domain and a nucleic acid fragment encoding a cellular

targeting signal peptide. Any small change in a catalytic domain could drastically alter the activity and structure. In addition, the catalytic domains are from different species. A search of one would not be co-extensive with a search of the other and hence would be burdensome.

Inventions XIV and XV are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions comprise a chimeric polypeptide and a nucleic acid encoding the polypeptide. Polypeptides are biochemically, functionally and structurally unrelated to nucleic acid sequences. A search of one would not be co-extensive with a search of the other and hence would be burdensome.

Inventions XVI and XVII are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions comprise different glycoproteins that are structurally and functionally different from each other. A search of one would not be co-extensive with a search of the other and hence would be burdensome.

Pursuant to 35 U.S.C. 121 and 37 C.F.R. 1.141, the sequences listed in Groups XVIII – XLII are subject to restriction. The Commissioner has partially waived the requirements of 37 C.F.R. 1.141 and will permit a reasonable number of such sequences to be claimed in a single application. Under this policy, a single independent and distinct sequence will be examined in a single application. The sequences are

considered to be unrelated since each sequence claimed is structurally and functionally independent and distinct for the following reasons: in the instant case, the claims are related because all of the groups contain nucleotide sequences, however, each group involves products not required by the other so that groups are not linked by a single feature. Distinctly different nucleotide sequences are structurally distinct chemical compounds and are deemed to normally constitute independent and distinct inventions within the meaning of 35 U.S.C. 121. Absent evidence to the contrary, each such nucleotide sequence is presumed to represent an independent and distinct invention, subject to a restriction requirement pursuant to 35 U.S.C. 121 and 37 CFR 1.141 et seq. Furthermore, a search of more than one (1) of the sequences claimed presents an undue burden on the Patent and Trademark Office due to the complex nature of the search and corresponding examination of more than one (1) of the claimed sequences. In view of the foregoing, one (1) sequence is considered to be a reasonable number of sequences for examination. Accordingly, applicant is required to elect one (1) sequence, therefore one group from the Groups listed above.

Inventions I, II and VII, VIII are related as process of making and product made. The inventions are distinct if either or both of the following can be shown: (1) that the process as claimed can be used to make other and materially different product or (2) that the product as claimed can be made by another and materially different process (MPEP § 806.05(f)). In the instant case the glycoprotein of Group VII is related to the process of making glycoproteins of Group I, and the N-glycan is related to the process

of making N-glycans of Group II, however, other processes can be used to make glycoproteins and N-glycans, such as mammalian expression systems.

Except for the specific relationships described above, the inventions of Groups I-II and III- XIII and XIV-XV and XVIII- XLII are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the methods of producing a glycoprotein or N-glycan of Groups I-II are not used with the products of groups III- XIII and XIV-XV and XVIII- XLII. A search of one would not be co-extensive with a search of the other and hence would be burdensome.

Because these inventions are distinct for the reasons given above and have acquired a separate status in the art because of their recognized divergent subject matter, restriction for examination purposes as indicated is proper.

Claims 6, 8, 11 and 13 are generic to a plurality of disclosed patentably distinct species comprising an oligosaccharide to be used as a substrate in the methods of Groups I and II to produce a glycoprotein or N-glycan. Applicant is required under 35 U.S.C. 121 to elect a single disclosed species, even though this requirement is traversed.

Claims 38 and 56 are generic to a plurality of disclosed patentably distinct species comprising a vector to be used in the construction of a nucleic acid library of

Groups II -XIII. Applicant is required under 35 U.S.C. 121 to elect a single disclosed species, even though this requirement is traversed.

Claim 23 is generic to a plurality of disclosed patentably distinct species comprising a mannosidase to be used in the methods of Groups I and II to produce a glycoprotein or N-glycan. Applicant is required under 35 U.S.C. 121 to elect a single disclosed species, even though this requirement is traversed.

Claim 27 is generic to a plurality of disclosed patentably distinct species comprising a host cell to be used in the methods of Groups I and II to produce a glycoprotein or N-glycan. Applicant is required under 35 U.S.C. 121 to elect a single disclosed species, even though this requirement is traversed.

Claim 30 is generic to a plurality of disclosed patentably distinct species comprising a therapeutic protein, a product of the methods of Groups I and II to produce a glycoprotein or N-glycan. Applicant is required under 35 U.S.C. 121 to elect a single disclosed species, even though this requirement is traversed.

Claim 33 is generic to a plurality of disclosed patentably distinct species comprising a nucleic acid fragment encoding a target polypeptide to be used in the construction of a nucleic acid library of Groups II -XIII. Applicant is required under 35 U.S.C. 121 to elect a single disclosed species, even though this requirement is traversed.

Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the

case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

The examiner has required restriction between product and process claims. Where applicant elects claims directed to the product, and a product claim is subsequently found allowable, withdrawn process claims that depend from or otherwise include all the limitations of the allowable product claim will be rejoined in accordance with the provisions of MPEP § 821.04. **Process claims that depend from or otherwise include all the limitations of the patentable product** will be entered as a matter of right if the amendment is presented prior to final rejection or allowance, whichever is earlier. Amendments submitted after final rejection are governed by 37 CFR 1.116; amendments submitted after allowance are governed by 37 CFR 1.312.

In the event of rejoinder, the requirement for restriction between the product claims and the rejoined process claims will be withdrawn, and the rejoined process claims will be fully examined for patentability in accordance with 37 CFR 1.104. Thus, to be allowable, the rejoined claims must meet all criteria for patentability including the requirements of 35 U.S.C. 101, 102, 103, and 112. Until an elected product claim is found allowable, an otherwise proper restriction requirement between product claims and process claims may be maintained. Withdrawn process claims that are not commensurate in scope with an allowed product claim will not be rejoined. See "Guidance on Treatment of Product and Process Claims in light of In re Ochiai, In re Brouwer and 35 U.S.C. § 103(b)," 1184 O.G. 86 (March 26, 1996). Additionally, in order

to retain the right to rejoinder in accordance with the above policy, Applicant is advised that the process claims should be amended during prosecution either to maintain dependency on the product claims or to otherwise include the limitations of the product claims. **Failure to do so may result in a loss of the right to rejoinder.** Further, note that the prohibition against double patenting rejections of 35 U.S.C. 121 does not apply where the restriction requirement is withdrawn by the examiner before the patent issues. See MPEP § 804.01.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Michele K. Joike, Ph.D. whose telephone number is 571-272-5915. The examiner can normally be reached on M-F, 8:30-6:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Irem Yucel, Ph.D. can be reached on 571-272-0781. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Michele K Joike, Ph.D.
Examiner
Art Unit 1636

DAVID GUZO
PRIMARY EXAMINER